SECTION 3 – 510(k) SUMMARY

k060876

JUN 15 2006

Submission Correspondent: Roche Diagnostics
Address: 9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457
USA

Contact: Scott Thiel
Regulatory Affairs Project Principal
Phone: (800) 428-5074 X13362
Fax: (317) 521-2324
E Mail: scott.thiel@roche.com

Submission Sponsor: Disetronic Medical Systems AG
Kirchbergstrasse 190
CH-3401 Burgdorf
Switzerland

Date Prepared: March 30, 2006

Trade Name: ACCU-CHEK® Spirit Insulin Infusion Pump

Common Name: Insulin infusion pump and accessories

Classification: Pump, infusion, insulin

Regulation # 21 CFR 880.5725

Product Code LZG

Class II device

Description: The ACCU-CHEK Spirit Insulin Infusion Pump is an ambulatory, battery operated insulin pump designed for continuous delivery of insulin. The design allows for delivery of 0.0 to 25.0 units of U100 insulin per hour in basal rates and up to 25.0 units of U100 insulin per meal or meal bolus. The pump is made of impact resistant plastic. The pump is compatible with commercially available subcutaneous administration sets with standard female luer connectors.

The ACCU-CHEK Spirit Insulin Infusion Pump is equipped with an IR-Interface in order to enable data transmission between the

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pump and a personal computer. The ACCU-CHEK Insulin Pump Configuration Software facilitates the monitoring and programming of the pump settings.

Intended Use: The ACCU-CHEK Spirit Insulin Infusion Pump is intended for the subcutaneous continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin as prescribed by a physician. The ACCU-CHEK Insulin Pump Configuration Software facilitates the monitoring and programming of the pump settings.

Predicate Devices: The ACCU-CHEK Spirit Insulin Infusion Pump in this submission is a modification to the predicate device of the same name with 510(k):

510(k) #: K042887
ACCU-CHEK Spirit Insulin Infusion Pump
Disetronic Medical Systems AG
Cleared on March 18, 2005

Safety and Effectiveness:

The ACCU-CHEK Spirit Insulin Infusion Pump has the same indications for use, and features as the previously cleared device. The addition of the ACCU-CHEK Insulin Pump Configuration Software facilitates the monitoring and programming of the pump settings. The software has been verified and validated and no new issues were raised regarding safety and effectiveness.

Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The ACCU-CHEK Spirit Insulin Infusion Pump has the same indications for use, and features as the previously cleared device, with the addition of the Insulin Pump Configuration Software for use in programming the ACCU-CHEK Spirit Insulin Infusion Pump and monitoring data collected on the ACCU-CHEK Spirit Insulin Infusion Pump. Based on the design equivalency and the software testing performed, we have determined that the implementation of the ACCU-CHEK Insulin Pump Configuration Software for the ACCU-CHEK Spirit Insulin Infusion Pump to be substantially equivalent to the predicate device currently cleared via K042887.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2006

Disetronic Medical Systems AG
C/O Mr. Scott Thiel
Regulatory Affairs Project Principal
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46250-0457

Re: K060876
Trade/Device Name: ACCU-CHEK® Spirit Insulin Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: March 30, 2006
Received: March 31, 2006

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

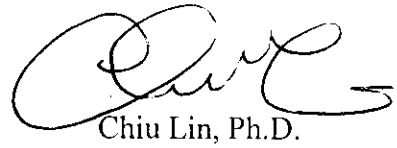
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060876

Device Name: ACCU-CHEK® Spirit Insulin Infusion Pump

The ACCU-CHEK Spirit Insulin Infusion Pump is intended for the subcutaneous continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin as prescribed by a physician. The ACCU-CHEK Insulin Pump Configuration Software facilitates the monitoring and programming of the pump settings.

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

[illegible]
[illegible] Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices
[illegible]Number K060876